

# Evidence-based diabetes nutrition therapy recommendations are effective: the key is individualization

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**Abstract:** Current nutrition therapy recommendations for the prevention and treatment of diabetes are based on a systematic review of evidence and answer important nutrition care questions. First, is diabetes nutrition therapy effective? Clinical trials as well as systematic and Cochrane reviews report a ~1%–2% lowering of hemoglobin A<sub>1c</sub> values as well as other beneficial outcomes from nutrition therapy interventions, depending on the type and duration of diabetes and level of glycemic control. Clinical trials also provide evidence for the effectiveness of nutrition therapy in the prevention of diabetes. Second, are weight loss interventions important and when are they beneficial? Modest weight loss is important for the prevention of type 2 diabetes and early in the disease process. However, as diabetes progresses, weight loss may or may not result in beneficial glycemic and cardiovascular outcomes. Third, are there ideal percentages of macronutrients and eating patterns that apply to all persons with diabetes? There is no ideal percentage of macronutrients and a variety of eating patterns has been shown to be effective for persons with diabetes. Treatment goals, personal preferences (eg, tradition, culture, religion, health beliefs, economics), and the individual's ability and willingness to make lifestyle changes must all be considered by clinicians and/or educators when counseling and educating individuals with diabetes. A healthy eating pattern emphasizing nutrient-dense foods in appropriate portion sizes, regular physical activity, and support are priorities for all individuals with diabetes. Reduced energy intake for persons with prediabetes or type 2 diabetes as well as matching insulin to planned carbohydrate intake are intervention to be considered. Fourth, is the question of how to implement nutrition therapy interventions in clinical practice. This requires nutrition care strategies.

**Keywords:** diabetes nutrition therapy, macronutrients, eating patterns, weight loss interventions

## Introduction

The nutrition therapy recommended for people with diabetes is often based on theories or the opinions of the medical treatment provider. People with diabetes often find this frustrating or confusing, because they hear or read that ideally they should be on a low-carbohydrate diet but from other sources they are told that they should be eating a high-carbohydrate, high-protein, or low-fat diet. However, in recent years, there has been a shift in how medical recommendations for prevention and treatment of various diseases are developed. Medical recommendations, including those for nutrition therapy, are now being developed using an evidence-based approach. The Academy of Nutrition and Dietetics published evidence-based nutrition recommendations for type 1 and type 2 diabetes in 2010<sup>1,2</sup> and the American Diabetes Association (ADA)

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in 2013 published nutrition therapy recommendations for the management of adults with diabetes using a similar process.<sup>3</sup> The ADA 2013 nutrition therapy recommendations are the basis for the majority of the recommendations cited in this review.

The goals of diabetes nutrition therapy are nutrition interventions that promote healthy eating and assist in achieving glucose, lipid, and blood pressure goals.<sup>1-3</sup> The present paper reviews the updated diabetes nutrition therapy recommendations and several of the questions asked that determine the recommendations for achievement of the diabetes nutrition therapy goals in clinical practice. The first question, and perhaps the most important, is what is the evidence that nutrition therapy for persons with diabetes is effective, and if effective, what nutrition interventions result in positive health outcomes? An important second question is what is the role of weight loss interventions across the continuum of diabetes, from prevention of the disease to its management? Third, are there ideal percentages of macronutrients or eating patterns that should be recommended to persons with diabetes? Fourth, how can health professionals individualize and implement these recommendations when providing nutrition care for patients with diabetes?

## Effectiveness of nutrition therapy

Multiple studies provide evidence that diabetes nutrition therapy is effective for improving glycemic control and other metabolic outcomes. Because it reflects average glycemia over several months, hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) is used to assess glycemic control. Nutrition therapy interventions implemented by registered dietitians/nutritionists reduced HbA<sub>1c</sub> levels by an average of 1% to 2% (range -0.23% to -2.6%) depending on the type and duration of diabetes and the HbA<sub>1c</sub> level at implementation.<sup>1-4</sup> For example, implementation of nutrition therapy in patients with newly diagnosed type 2 diabetes and an HbA<sub>1c</sub> of ~9% resulted in a decrease of ~2%,<sup>5</sup> whereas persons newly diagnosed with HbA<sub>1c</sub> levels of ~6.6% experienced a decrease of 0.4%,<sup>6</sup> both of which are significant and clinically meaningful. Even in patients with a long duration of type 2 diabetes of ~9 years and diabetes that was not optimally controlled, implementation of nutrition therapy decreased HbA<sub>1c</sub> by ~0.5%, which was significant and more cost-effective than adding a third medication.<sup>7</sup> In persons with type 1 diabetes, implementation of nutrition therapy based on adjustments in insulin to cover carbohydrate intake improved HbA<sub>1c</sub> by ~1% and improved quality of life without worsening of hypoglycemia or cardiovascular risk.<sup>8</sup> Other studies in subjects with type 1 or type 2 diabetes have reported similar beneficial glycemic results

that are maintained and other beneficial outcomes, including improved lipid profiles, weight loss, decreased blood pressure, decreased need for medication, and decreased risk of onset and progression to diabetes-related comorbidities.<sup>4</sup>

Of interest are the types of nutrition therapy interventions implemented, ie, reduced energy/fat intake, carbohydrate counting, simplified meal plans, healthy food or exchange choices, use of insulin-to-carbohydrate ratios, physical activity, and behavioral strategies. A unifying focus of nutrition therapy interventions for type 2 diabetes is a reduced energy intake and, for type 1 diabetes, adjusting insulin based on carbohydrate counting.<sup>2</sup> It is essential that the person with diabetes be actively involved with health professionals to collaboratively develop appropriate nutrition interventions and an individualized eating pattern that they can implement. The ADA recommends that persons with diabetes receive individualized medical nutrition therapy as needed to achieve treatment goals, preferably by a registered dietitian/nutritionist familiar with the components of medical nutrition therapy in diabetes.<sup>3</sup> Multiple encounters to provide education and counseling initially and on a continued basis are also essential.<sup>4</sup>

Diabetes nutrition education can also be provided as part of a comprehensive diabetes self-management and support program.<sup>3</sup> Unfortunately, national data in the US indicate that only about a half of persons with diabetes receive diabetes education and even fewer see a registered dietitian/nutritionist.<sup>9</sup> One study of over 18,000 people with diabetes revealed that only 9.1% had at least one nutrition visit within a 9-year period of time.<sup>10</sup> It is likely the same problem exists in other countries as well. Disease self-management, support, and nutrition therapy are important components of diabetes care and necessary for improved outcomes in all people with the disease.<sup>11-14</sup>

## Weight loss intervention

Overweight and obesity are common health problems in persons at risk for and with type 2 diabetes. Weight loss is frequently recommended as the solution to improve glycemic control.<sup>3</sup> In persons with prediabetes, modest amounts of weight loss and regular physical activity are very effective in preventing or delaying the onset of type 2 diabetes.<sup>15</sup> In individuals who have maintained lifestyle strategies for prevention of diabetes, the effectiveness of these strategies has been maintained for 10 years and longer.<sup>16</sup> Weight loss interventions have also been shown to be effective in improving glycemic control in individuals with newly diagnosed diabetes.<sup>17,18</sup>

The benefit of weight loss interventions in type 2 diabetes of longer duration is controversial.<sup>19</sup> The Academy of

Nutrition and Dietetics reported that approximately half of the weight loss intervention studies in persons with type 2 diabetes achieved improvements in HbA<sub>1c</sub> at one year and one half did not.<sup>2</sup> The ADA reported that in weight loss intervention studies lasting one year or longer in persons with diagnosed type 2 diabetes, modest weight losses ranged from 1.9 kg to 8.4 kg.<sup>3</sup> The two interventions resulting in the largest amount of weight loss at one year were the Mediterranean-style eating pattern (−6.2 kg) in persons with newly diagnosed diabetes<sup>18</sup> and the intensive lifestyle intervention in the Look AHEAD (Action For Health in Diabetes) trial (−8.4 kg), also in individuals who were early in the disease process.<sup>20</sup> The other weight loss interventions reviewed by the ADA resulted in weight losses of 4.8 kg or less at one year.<sup>3</sup> HbA<sub>1c</sub> levels improved at one year in six intervention groups; however, HbA<sub>1c</sub> levels at one year did not improve in six other intervention groups. Lipid and blood pressure outcomes from weight loss interventions were mixed.

The Look AHEAD trial<sup>20,21</sup> deserves review. The objective was to determine if long-term weight reduction would reduce cardiovascular morbidity and mortality in people with type 2 diabetes. The trial was stopped early in September 2012 after 9.6 years; although intensive lifestyle intervention did no harm, it was not on a trajectory that would result in greater decreases in cardiovascular events relative to the control group.<sup>22</sup> The weight loss and improvements in other metabolic outcomes were impressive; however, the feasibility of implementing intensive lifestyle intervention in clinical practice is unknown. Individuals on the intensive lifestyle intervention program were seen 3–4 times monthly during the first year and 1–2 times each month for the remainder of the trial. The majority were prescribed portion-controlled diets (liquid meal replacements or frozen food entrees) and structured meal plans for those who declined meal replacements.

In the majority of weight loss trials reviewed by the ADA, weight loss in overweight or obese persons with type 2 diabetes ranged from 1.9 kg to 4.8 kg at one year (less than 5% of baseline weight).<sup>3</sup> Although this is likely a realistic weight loss expectation for persons with diabetes, it did not result in consistent one-year improvements in HbA<sub>1c</sub>, lipids, or blood pressure. Furthermore, it appears to be more difficult for persons with diabetes to lose weight. In a systematic review of 80 studies with 26,455 participants primarily without diabetes, the average weight loss was ~7.5 kg (8% of baseline weight).<sup>23</sup>

Weight loss to improve glycemic control, therefore, may be most beneficial for persons with prediabetes or early in the

diabetes disease process. A weight loss of >6 kg (~7%–8.5% loss of initial body weight), regular physical activity, and frequent contact with registered dietitians appear to be important for consistent beneficial effects of weight loss interventions on glycemia, lipids, and blood pressure.<sup>19</sup> Health professionals should collaborate with individuals who have diabetes to integrate healthy lifestyle strategies that prevent weight gain or promote modest, realistic weight loss. Factors that contribute to an individual's inability to maintain weight loss include low socioeconomic status, an unsupportive environment, and physiologic changes (eg, compensatory changes in circulating hormones that encourage weight regain after weight loss is achieved).<sup>24</sup> Because nutrition therapy goals are broader than weight loss, nutrition therapy is essential throughout the disease process. For persons with type 2 diabetes, a nutrient-dense eating pattern that focuses on a reduced energy intake (which may or may not lead to weight loss), regular physical activity, and support for lifestyle changes should be the first priorities.

## Macronutrient percentages and eating patterns

In the US, the majority of persons with type 1 or type 2 diabetes report eating moderate amounts of carbohydrate (~45% of total energy intake) and ~35%–40% of energy intake from fat, with the remainder (~16%–18%) from protein.<sup>25</sup> Review of the evidence shows clearly that there is not an ideal percentage of calories from carbohydrate, protein, and fat for all persons with diabetes.<sup>3</sup> What emerges from the evidence is the importance of total energy intake rather than the source of the energy. However, even total energy intake is determined by the changes that the individual with diabetes is willing and able to make. Personal preferences (eg, tradition, culture, religion, health beliefs and goals, economics) and metabolic goals determine appropriate eating patterns for each individual, making individualization essential.

Because macronutrients require insulin for metabolism and influence the attaining of the goals of nutrition therapy, including healthy eating, they still must be addressed. The amount rather than type of carbohydrate and available insulin is the primary determinant of postprandial glycemia.<sup>1–3</sup> Monitoring carbohydrate intake, whether by carbohydrate counting or experience-based estimation, remains a key strategy in achieving glycemic control.<sup>3</sup> Although all carbohydrates can be incorporated into carbohydrate counting, for good health, carbohydrates from vegetables, fruits, whole grains, legumes, and dairy products take priority over other

carbohydrate sources, especially those that contain added fats, sugars, or sodium.<sup>3</sup>

The type of carbohydrates, especially the role of the glycemic index (GI) and glycemic load, has been another area of controversy. The definition of the GI has been an area of confusion in the US. The GI measures the relative area under the glucose curve, and does not measure how rapidly blood glucose levels increase after eating different carbohydrate-containing foods, which is the definition often given to the public. The second definition implies that a high-GI food produces a rapid, high glucose peak while a low-GI food produces a more gradual and sustained glucose response. In a review of studies comparing different types of low-GI and high-GI foods and glucose responses, glucose peaks occurred consistently at ~30 minutes, regardless of whether the food was categorized as low-GI, medium-GI, or high-GI, with a modest difference in glucose peak values between high-GI and low-GI foods.<sup>26</sup> The authors concluded that low-GI foods do not produce a slower rise in blood glucose nor do they produce an extended, sustained glucose response.

The systematic ADA review of macronutrients concluded that, in general, there is little difference between low-GI and high-GI or other diets in terms of glycemic control or cardiovascular risk.<sup>27</sup> The ADA review notes that a slight improvement in glycemia may result from a lower-GI diet; however, confounding by higher fiber is not accounted for in some of the studies. The Academy of Nutrition and Dietetics reviewed 15 studies and noted that 12 were of short duration (<3 months) with a limited number of subjects. Only three studies were of one year in duration. After one year, one study reported no difference in actual GI between the low-GI and control groups, and two studies reported no differences in HbA<sub>1c</sub> between the low-GI and control groups.<sup>12</sup> Both the ADA and Academy of Nutrition and Dietetics note that definition of low-GI versus high-GI diets is complicated by differing definitions of high-GI or low-GI diets or quartiles (for example, definition of low-GI diets range from 38% to 77% and definitions for high-GI diets range from 63% to 98%).<sup>1-3</sup> Other problems include the variability in GI response to carbohydrate-containing foods within and among individuals. As with carbohydrates, most individuals with diabetes appear to consume a moderate-GI diet, and it is unknown if reducing the usual GI by a few percentage points will result in improved glycemic control.<sup>27</sup>

It is recommended that people with diabetes should consume at least the amount of fiber and whole grains recommended for the public.<sup>1-3</sup> Because of the general health benefits of fiber, an increased fiber intake to 14 g/1,000 kcal daily

or about 25 g/day for adult women and 30 g/day for adult men is encouraged. Diets containing >50 g/day of fiber are reported to improve glycemia in persons with diabetes; however, more usual intakes (up to 24 g/day) have not shown beneficial effects on glycemia.<sup>3</sup> Studies examining the effect of fiber on cardiovascular risk are mixed.<sup>27</sup> Consumption of whole grains has not been associated with improved glycemic control in persons with diabetes; however, as for the general population, individuals with diabetes should consume at least half of all grains as whole grains.<sup>3</sup> Large prospective cohort studies, but not randomized controlled trials, report that consumption of whole grains is associated with a reduced incidence of type 2 diabetes.<sup>15</sup>

Sucrose-containing foods can be substituted for isocaloric amounts of other carbohydrate foods.<sup>1-3</sup> As for the general population, care should be taken to avoid excess energy intake and to avoid displacing nutrient-dense food choices.

For the first time, the ADA nutrition recommendations now specifically advise the avoidance of sugar-sweetened beverages.<sup>3</sup> These include soft drinks, fruit drinks, iced tea, and energy and vitamin water drinks containing sucrose, high-fructose corn syrup, and/or fruit juice concentrates.<sup>28</sup> Based on evidence from studies in people without diabetes, large quantities of sugar-sweetened beverages should be avoided to reduce the risk of worsening the cardiometabolic risk profile and to prevent weight gain.<sup>3,29</sup> Studies are not available for persons with diabetes; however, there is little reason to conclude that the diabetic state would mitigate the adverse effects of sugar-sweetened beverages.<sup>3</sup> The ADA also recommends that individuals at risk for type 2 diabetes be encouraged to limit their intake of sugar-sweetened beverages.<sup>29</sup> In a meta-analysis of cohort studies, individuals in the highest versus lowest quartile of sugar-sweetened beverage intake had a 26% greater risk of developing diabetes.<sup>30</sup>

Regarding the use of non-nutritive sweeteners and sugar alcohols, the US Food and Drug Administration reviewed several types and has approved them for consumption by the general public and persons with diabetes.<sup>31</sup> The ADA nutrition recommendations advise that use of non-nutritive sweeteners has the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners without compensation by intake of additional calories from other food sources.<sup>3</sup>

Gram for gram protein is reported to require similar amounts of insulin for metabolism as do carbohydrates.<sup>32</sup> Although non-essential amino acids undergo gluconeogenesis in the liver, the glucose does not enter the general circulation. Adding protein to bedtime snacks is often recommended to prevent overnight

hypoglycemia or is added to the treatment of hypoglycemia, but adding protein to prevent hypoglycemia or to the treatment of hypoglycemia is not beneficial and should not be recommended to persons with diabetes.<sup>3</sup> Also of interest is the role of protein restriction in the treatment of diabetic kidney disease. Although reducing protein intake below usual intake in individuals with microalbuminuria and macroalbuminuria has been shown to reduce albuminuria, it does not alter the glomerular filtration rate and therefore is not recommended.<sup>3</sup>

In terms of supporting or achieving metabolic goals and influencing the risk of cardiovascular disease, the type of fatty acids consumed is more important than total fat in the diet.<sup>3</sup> Individuals with diabetes are encouraged to select unsaturated fats in place of saturated and trans fatty acids and are encouraged to moderate their fat intake to be consistent with their goals to lose or maintain weight. The intake of foods rich in monounsaturated fatty acids as a component of a Mediterranean-style eating pattern was reported to improve glycemic control and/or serum lipids when monounsaturated fatty acids were substituted for carbohydrate and/or saturated fats.<sup>3</sup> However, some of the studies also included a reduced energy intake. Individuals with diabetes, like the general public, are encouraged to increase foods containing long-chain omega-3 fatty acids; specifically to eat at least two servings of fish, particularly fatty fish, per week.<sup>3</sup> However, the evidence does not support recommending omega-3 supplements for people with diabetes for the prevention or treatment of cardiovascular events.<sup>3</sup> A systematic review of seven randomized controlled trials and one single-arm study using omega-3 fatty acid supplements reported that supplementation did not improve glycemic control and blood-derived markers of cardiovascular risk were not consistently altered in these trials.<sup>27</sup> In a large 6-year study in patients with type 2 diabetes, supplementation with omega-3 fatty acids at 1 g/day did not reduce the rate of cardiovascular events, death from any cause, or death from arrhythmia in comparison with placebo.<sup>33</sup>

Of concern is the effect of total fat, especially saturated fat, on insulin sensitivity in persons with diabetes. Epidemiologic data and clinical trials have reported that long-term higher total fat intake results in greater whole-body insulin resistance.<sup>34,35</sup> Although not as well studied in persons with diabetes, reducing saturated fat has been shown to improve insulin sensitivity.<sup>36,37</sup> The impact of long-term intake of saturated fatty acids on insulin resistance is important because as people with diabetes decrease their intake of carbohydrate, they increase their fat intake, especially of saturated fat.<sup>38</sup>

Recommendations for alcohol consumption for people with diabetes are the same as those for the general population. Adults

choosing to consume alcohol should limit their intake to one serving or less per day for women and two servings or less per day for men.<sup>3</sup> One alcohol-containing beverage is defined as 1.5 ounces of distilled spirits, 5 ounces of wine, or 12 ounces of beer, each containing approximately 15 grams of ethanol. Moderate alcohol consumption has minimal detrimental acute and/or long-term effects on blood glucose in people with diabetes. Studies of alcohol consumption in persons with diabetes report a U-shaped or J-shaped association, suggesting a benefit from moderate consumption.<sup>39,40</sup> Moderate consumption in people with type 2 diabetes is also reported to be associated with a reduced risk of and mortality from coronary heart disease and lower total mortality rates,<sup>41</sup> likely related to improved insulin sensitivity.<sup>42</sup> The type of alcoholic beverage does not influence the beneficial effects on glycemia and reduction of cardiovascular risk in people with diabetes.<sup>43</sup> Abstinence is of course recommended for people with risks related to alcohol consumption.

Many micronutrients are involved in carbohydrate and/or glucose metabolism as well as with insulin release and sensitivity. Unfortunately, the public is frequently given messages about their benefits, and some surveys indicate that up to 60% of people with diabetes in the US use some form of alternative medicine.<sup>44</sup> The ADA review concluded that there is no clear evidence of benefits from vitamin or mineral supplementation in people with diabetes who do not have underlying deficiencies.<sup>3</sup> Without well designed clinical trials to prove their efficacy, the benefits of pharmacologic doses of herbs/supplements are unknown. Unfortunately, findings from small clinical trials and animal studies are frequently extrapolated to clinical practice.<sup>45</sup>

Recommendations for sodium intake in persons with diabetes have been an area of controversy. A Cochrane review of randomized clinical trials reported that decreasing sodium intake reduced blood pressure in those with diabetes.<sup>46</sup> The ADA concluded that incrementally lower sodium intakes (ie, to 1,500 mg/day) had a beneficial effect on blood pressure; however, some studies in people with type 1 or type 2 diabetes measuring urinary sodium excretion (suggesting a lower sodium intake) reported increased all-cause and cardiovascular mortality rates.<sup>3</sup> Acknowledgement is made regarding the difficulty in achieving both low sodium recommendations and a nutritionally adequate diet.<sup>47</sup> Therefore, in the absence of clear scientific evidence for a benefit in people with both diabetes and hypertension, the recommendations for the general public to reduce sodium to less than 2,300 mg/day is considered to be appropriate for people with diabetes.<sup>3</sup> Sodium goals significantly lower than this should be considered only on an individual basis.

Just as people with diabetes do not eat a single type of macronutrient, they do not eat a single type of food. Foods are consumed in combinations, and thus it is important to review the relationship between eating patterns (combinations of different foods or food groups) and disease. The ADA reviewed research studies on Mediterranean-style, vegetarian and vegan, low-fat, low-carbohydrate, and DASH (Dietary Approaches to Stop Hypertension, ie, the diet used in hypertension studies) eating patterns that included participants with diabetes, and concluded that a variety of eating patterns are acceptable for the management of diabetes.<sup>3</sup> Personal preferences (eg, tradition, culture, religion, health beliefs and goals, economics) and metabolic goals should be considered when recommending one eating pattern over another.

## Implementing effective and individualized nutrition therapy

The ADA 2013 nutrition therapy recommendations provide a summary of priority topics for persons with diabetes. Key strategies for all people with diabetes include:<sup>3</sup>

- portion control of all foods with an emphasis on choosing nutrient-dense, high-fiber foods whenever possible instead of processed foods with added sodium, fat, and sugars; avoid sugar sweetened beverages, select leaner protein sources and meat alternatives, and substitute foods higher in unsaturated fat (liquid oils) for foods high in trans or saturated fats
- vitamin and mineral supplements, herbal products, or cinnamon are not recommended for management of diabetes
- limit sodium intake to 2,300 mg/day
- moderate alcohol consumption (one drink/day or less for adult women and two drinks or less for adult men) has minimal acute or long-term effects on blood glucose and may have beneficial effects on cardiovascular risk; to reduce the risk of hypoglycemia for individuals using insulin or insulin secretagogues, alcohol should be consumed with food.

Key strategies for individuals requiring medications or insulin include:

- eating moderate amounts of carbohydrate at meals (and snacks, if desired)
- not skipping meals.

Key strategies for individuals with type 1 diabetes or insulin-requiring type 2 diabetes are:

- learning to use carbohydrate counting or another meal planning approach to quantify carbohydrate intake; the objective is to “match” mealtime insulin to planned carbohydrate consumption

- if on a multiple-daily injection plan or an insulin pump, take mealtime insulin before eating
  - if on a premixed or fixed insulin plan, meals need to be eaten at similar times every day and contain similar amounts of carbohydrate that match set doses of insulin
- Individualizing key strategies for persons with diabetes include<sup>3</sup>:
- assessment of the individual’s current eating pattern, preferences, and metabolic goals
  - development of nutrition therapy goals collaboratively with the individual
  - selecting a meal planning approach or eating pattern based on the individual’s personal and cultural preferences, their literacy and numeracy, and their readiness, willingness, and ability to change
  - facilitating behavioral change and achievement of metabolic goals while meeting the patient’s preferences
  - monitoring outcomes and providing ongoing support; recommendations may need to be adjusted over time based on changes in life circumstance, preferences, and disease course.

## Summary

Strong evidence supports the effectiveness of nutrition therapy across the continuum of diabetes management. Weight loss interventions are most effective for improving glycemic control in persons with prediabetes and individuals newly diagnosed with diabetes. For all people with diabetes, the goals of nutrition therapy are to assist in achieving and maintaining glucose, lipids, and blood pressure goals. The nutrition therapy interventions selected must meet the individual’s goals and lifestyle and be strategies that the individual with diabetes is willing and able to implement.

## Disclosure

The authors report no conflicts of interest in this work.

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